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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC. AND RAREGEN, LLC, Plaintiffs, V. UNITED THERAPEUTICS CORPORATION AND SMITHS MEDICAL ASD, INC., Defendants.	Civil Action No. 3:19-cv-10170-BRM-LHG Document filed electronically **Oral argument requested** Motion return date: July 1, 2019

DEFENDANTS' BRIEF IN SUPPORT OF MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(6)

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INTRODUCTION

Defendants Smiths Medical ("Smiths") and United Therapeutics Corp. ("UTC") move to dismiss Plaintiffs' claims under Rule 12(b)(6) because they fail to state any basis upon which relief might be granted. Plaintiffs' claims under Sections 1 and 2 of the Sherman Act fail on multiple, independent fronts. First, Plaintiffs fail to allege there are no reasonable alternatives to the drug-delivery devices that are the subject of the suit. To the contrary, the Complaint acknowledges that alternatives can be, have been, and are being developed. Compl. ¶¶ 40–44. Second, Plaintiffs admit that UTC's exclusivity arrangements were necessary to secure its own supply of the devices—that is, they were procompetitive. Because Plaintiffs have not pled that they were substantially foreclosed from the market, and have not pled facts supporting a plausible inference that UTC's and Smiths's actions were anticompetitive, Plaintiffs' federal antitrust claims fail. Plaintiffs' allegations also demonstrate that Plaintiff RareGen, LLC has no claim to direct injury and therefore lacks antitrust standing. Finally, Plaintiffs' four state law claims also should be dismissed. Three are entirely duplicative of Plaintiffs' antitrust claims and fail along with them, and the fourth fails because UTC's and Smiths's actions were commercially reasonable and thus are privileged under applicable law.

* * *

Several thousand patients in the United States rely on a life-sustaining drug called "Remodulin® (treprostinil) Injection" ("Remodulin") to treat advanced stages of a deadly disease, pulmonary arterial hypertension ("PAH"). Roughly half of these patients receive their Remodulin subcutaneously via the CADD-MS® 3 pump and associated cartridges manufactured by Smiths. In 2015, Smiths issued an "end-of-life" notice, announcing that it would soon stop manufacturing the CADD-MS 3 pump and associated cartridges. UTC, which manufactures

Remodulin, took immediate action to ensure that PAH patients would have uninterrupted access to CADD-MS 3 pumps and cartridges: UTC contracted with Smiths in early-2016 and agreed to fund Smiths' continued manufacture of pumps and cartridges. But for UTC taking on this financial burden and market risk, Smiths would have stopped manufacturing the pumps and cartridges, and neither the CADD-MS 3 pumps nor the necessary cartridges would have been available to *any* patients. In exchange for funding the continued manufacture of the CADD-MS 3 line, UTC asked for exclusive access to the resulting products—the products whose very existence it had made possible and paid for.

Plaintiff Sandoz Inc. ("Sandoz"), one of the world's largest drugmakers, has been preparing a generic copy of Remodulin since at least 2011. Yet Plaintiffs' Complaint does not allege that it took any timely steps to determine whether it would be able to use the CADD-MS 3 system to deliver its drug. Nor does Sandoz allege it took any steps to avail itself of other existing delivery systems suitable to administer its drug subcutaneously, or to work with a pump manufacturer to modify an existing or develop a new delivery system, as it admits UTC did. Sandoz was content, it appears, to let UTC bear all the risk and burden of making the CADD-MS 3 system available for years past its planned end-of-life, and then ask the Court to order UTC to provide Sandoz that which it could have obtained on its own through a modicum of diligence and effort. The law does not reward—nor should it—Sandoz's indolence.

But the Court need not delve into the merits of this dispute, because Plaintiffs' Complaint fails to state any legally cognizable claims and should be dismissed.

BACKGROUND

PAH is an almost invariably progressive, fatal disease that causes high blood pressure in the blood vessels of the lungs. Compl. ¶ 2. UTC's business is primarily focused on developing

therapies for PAH, and over the last two decades it has brought to market several medicines to treat various stages of PAH. *Id.* ¶ 10. The first medicine developed by UTC, Remodulin, is used to treat patients with more advanced PAH. *Id.* ¶ 17–18. Remodulin is administered to patients either intravenously or subcutaneously. *Id.* ¶ 19. In either application, patients use an external pump to continuously inject minute doses of Remodulin. Defendant Smiths manufactures pumps suitable for Remodulin injection. *Id.* ¶ 20. Approximately 2000 patients in the United States use subcutaneously administered Remodulin to treat their PAH. *Id.* ¶ 61. Most of those patients use the Smiths CADD-MS 3 pump and cartridges. *Id.* ¶ 21.

1. When Smiths Announced the End-of-Life of the CADD-MS 3, UTC Stepped Up and Paid To Keep the Line Open and Ensure Availability for Remodulin Patients.

In 2015, Smiths announced that it was planning to discontinue production of the CADD-MS 3 pump and associated cartridges. Compl. ¶ 51; Dkt. 11-4 (2018 UTC Form 10-K) at 8.[1] UTC rushed to ensure continued availability of the CADD-MS 3 and cartridges *and* continued its efforts to develop next-generation pumps to replace the CADD-MS 3 and other intravenous and subcutaneous pumps used by PAH patients. *Id.* First, UTC agreed to fund Smiths's continued production of the CADD-MS 3 and cartridges to ensure a supply for years to come. *Id.* If UTC had not taken this action, the supply of pumps and cartridges would have run out well before

[1] For purposes of this motion, Defendants accept as true the facts properly pled in the Complaint. Plaintiffs explicitly discuss the Smiths end-of-life notice and other of Defendants' statements, including by quoting isolated snippets from UTC's Form 10-K in the Complaint. *See, e.g.*, Compl. ¶¶ 51, 59. In deciding Defendants' motion to dismiss, it is appropriate for the Court to consider the full context of the documents quoted by Plaintiffs. *See, e.g.*, *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (court may consider documents "integral to or explicitly relied upon in the complaint," so that plaintiff cannot support claim "by extracting an isolated statement from a document and placing it in the complaint" when "full context of the document" reveals that the statement is unsupportive); *Young v. Johnson & Johnson*, 2012 WL 1372286, at *3 (D.N.J. Apr. 19, 2012) (considering document that plaintiff "relied on and quoted from" in complaint at motion to dismiss stage), *aff'd*, 525 F. App'x 179 (3d Cir. 2013).

Plaintiffs came to market in March 2019. *See id.* Second, UTC worked to develop several more advanced pumps to deliver Remodulin. *Id.*; Compl. ¶¶ 40, 42, 44. For example, UTC worked with Medtronic, Inc. on a highly advanced implantable pump that would be suitable for subcutaneous patients who might choose to adopt it. Compl. ¶ 40. UTC also worked with DEKA Research and Development Company on an advanced external pump that would replace the CADD-MS 3 for many subcutaneous Remodulin patients. *Id.* ¶ 42. UTC also worked with Smiths on a next-generation infusion system for both intravenous and subcutaneous Remodulin. *Id.* ¶ 44. And UTC acquired SteadyMed Ltd., which was working on yet another pump option for subcutaneous Remodulin patients. *Id.*

2. Sandoz Did Not Secure Pumps or Cartridges for Its Patients, Relying Instead on Litigation To Remedy Its Inaction.

In 2011, Sandoz, a subsidiary of the Swiss pharmaceutical giant Novartis, *see* Dkt. 2, filed an Abbreviated New Drug Application ("ANDA"), seeking approval for a generic version of Remodulin (referred to by its chemical name, treprostinil). Compl. ¶ 34. Sandoz sought FDA approval for both intravenous and subcutaneous use of treprostinil, *id.*, and therefore as a sophisticated drug company must have been aware of the various devices used to deliver the medication in those modes, that half of the treprostinil/Remodulin patients receive their medication subcutaneously, and that most of the subcutaneous patients use the Smiths CADD-MS 3 pump and cartridges. *See id.* ¶¶ 2, 19–21.

After years of patent litigation regarding the ANDA application, in 2015 UTC and Sandoz settled, agreeing that Sandoz could start marketing its generic drug in June 2018. *Id.* ¶¶ 36–37. For reasons Sandoz does not disclose, it was unprepared—despite the passage of many years—to come to market in June 2018. It did not even begin to prepare to enter the market until the end of 2018, *id.* ¶ 46, and did not launch until March 25, 2019, *id.* ¶ 24.

A few months after Sandoz missed its June 2018 launch date, Plaintiff RareGen LLC ("RareGen") was formed by a group that included two former UTC executives, Roger Jeffs and Scott Moomaw. *See id.* ¶ 45 (alleging that Sandoz and RareGen partnered in August 2018 to market Sandoz's generic drug).[2] One of RareGen's first corporate acts in August 2018 was to hire antitrust litigation counsel. Dkt. 6-3 (Decl. of Peter Calamari) ¶ 3 ("There has been an attorney-client relationship between Quinn Emanuel and RareGen since August 2018, and this case in which I seek admission involves a complex area of law in which I specialize (i.e. antitrust law).") A few months after engaging litigation counsel during the summer of 2018, Plaintiffs began to complain about the exclusivity agreements relating to the pumps and cartridges Smiths had manufactured specifically for—and because of—UTC. Compl. ¶¶ 47–48.

Although Plaintiffs' Complaint is full of conclusory, self-serving, and inflammatory statements, Plaintiffs proffer no evidence that a single PAH patient has been denied access to treprostinil because of Defendants' exclusive arrangement regarding the UTC-funded pumps and cartridges. Nor could they. The fact is that no patient has been denied treatment. More to the point, the only reason any patient still has access to the CADD-MS 3 pumps and associated cartridges is because UTC years ago took on the risk and financial burden of paying Smiths to keep its production lines open. *Id.* ¶ 51.

Sandoz has been developing its generic drug for approximately a decade. During that decade, as the Complaint acknowledges, UTC has been hard at work developing new therapies and ensuring that Remodulin patients would have an unbroken supply of pumps for subcutaneous use. The Complaint, in contrast, does not allege that Plaintiffs took any steps from

[2] The role of former UTC executives and employees in RareGen's competing business is noted for context only; it is not necessary to and should not be relied on in deciding Defendants' motion to dismiss.

2011 until the end of 2018 to secure a subcutaneous delivery device for generic treprostinil. Indeed, the Complaint details the steps UTC took to make several subcutaneous pumps available to PAH patients. *Id.* ¶¶ 40–44. Yet Plaintiffs do not allege that they took *any* similar steps at any time—much less after the 2015 CADD-MS 3 end-of-life announcement—to secure a supply of delivery systems (either pumps and cartridges or more advanced cartridge-less pumps). Moreover, Plaintiffs do not allege that there was any impediment preventing them from doing so—much less any impediment caused by Defendants UTC or Smiths. And Plaintiffs do not—because they cannot—allege that there are not other pumps or delivery systems suitable for subcutaneous treprostinil injection.

ARGUMENT

I. The Court Should Dismiss Plaintiffs' Antitrust Claims Because Plaintiffs Do Not Allege Defendants Foreclosed Them from Any Market.

Plaintiffs' antitrust claims all fail because Plaintiffs do not and cannot allege they were foreclosed from any market. Plaintiffs' antitrust claims all depend upon the proposition that without access to the CADD-MS 3 pumps and cartridges, Plaintiffs have no way to access the market for treprostinil administered subcutaneously.[3] But Plaintiffs fail to allege they lacked an alternative means of reaching the market: They do not allege there was no alternative to the CADD-MS 3 for the subcutaneous administration of treprostinil, or that they engaged in some effort to secure access to an alternative pump and cartridges but were unable to do so. Moreover, the Complaint does allege that Sandoz has known for many years it would be legally entitled to enter the market in June 2018, and that UTC has for years been engaging in joint development projects with pump manufacturers to develop alternatives to the CADD-MS 3 (and thus it must

[3] Defendants do not concede that the subcutaneous injection of treprostinil is a proper antitrust market, but assume it for purposes of this Motion only.

be inferred that Sandoz could readily have done likewise). These allegations demonstrate why Plaintiffs cannot plausibly allege they have no option other than to rely upon the supply of CADD-MS 3 pumps and cartridges that existed only because UTC funded their creation. If Plaintiffs lack options, it is because of their own inaction.

A. Plaintiffs' Antitrust Claims Require That They Properly Allege Foreclosure.

The gravamen of each of Plaintiffs' antitrust claims is that UTC and Smiths entered into exclusive agreements with each other and with specialty pharmacies or distributors that restricted the distribution of CADD-MS 3 pumps and cartridges to UTC's patients only, rendering them unavailable to Sandoz and RareGen to use with generic treprostinil. Compl. ¶¶ 79, 84, 89, 93.[4] The law recognizes that "in many circumstances [exclusive dealing arrangements] may be highly efficient—to assure supply, price stability, outlets, investment, best efforts or the like—and pose no competitive threat at all." *Races Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010) (quoting *E. Food Servs., Inc. v. Pontifical Catholic Univ. Ass'n, Inc.*, 357 F.3d 1, 8 (1st Cir. 2004)). Such arrangements can be unlawful only if they "foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012) (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961)).

If Plaintiffs had alternative means to reach the market, they cannot state an antitrust claim, because "the antitrust laws are enforced to protect competition and not individual competitors." *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 342 (3d Cir. 2018) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977)). And competition

[4] *See also* Compl. ¶¶ 47–49 (alleging that, in furtherance of exclusive arrangement with UTC, Smiths sold cartridges to specialty pharmacies and distributors on condition that they be used only with UTC's Remodulin patients; and that Smiths sold its full supply of cartridges to UTC).

could not have been harmed if Plaintiffs had alternate means to reach the market. *See, e.g.*, *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407–08 (3d Cir. 2016) (because "customers had the ability to switch to competing products" to avoid anticompetitive prices brought on by Defendant's allegedly anticompetitive conduct, Plaintiffs failed to establish harm to competition); *see also Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997) ("If competitors can reach the ultimate consumers of the product by employing existing or potential alternative channels of distribution, it is unclear whether such restrictions foreclose from competition *any* part of the relevant market."). That is the case whether allegations of exclusive dealing are made under § 1 or § 2 of the Sherman Act. *See, e.g.*, *U.S. v. Dentsply Int'l, Inc.*, 399 F.3d 181, 196 (3d Cir. 2005) (court must assess "overall significance to the market" of "other avenues of distribution" in § 2 exclusive dealing case).

In light of the foregoing precepts, courts recognize that a "fail[ure] to adequately plead the lack of alternative channels of distribution" is fatal to an exclusive dealing claim and necessitates its dismissal. *Int'l Constr. Prods. LLC v. Caterpillar, Inc.*, 2016 WL 264909, at *5 (D. Del. May 1, 2016); *see, e.g.*, *Am. Nat'l Mfg. v. Select Comfort Corp.*, 2016 WL 9450472, at *7 (C.D. Cal. Sept. 28, 2016) (plaintiff failed to sufficiently allege exclusive dealing claim under § 2 because it failed to allege that an exclusive supply agreement between defendants foreclosed it from alternative supplies); *Granite Partners, L.P. v. Bear Stearns & Co.*, 17 F. Supp. 2d 275, 296 (S.D.N.Y. 2011) (to survive motion to dismiss, § 1 claim must allege "that no reasonable alternative source is available"); *see also FTC v. Qualcomm Inc.*, 2017 WL 2774406, at *7 (N.D. Cal. June 26, 2017) ("[W]hether bringing claims under § 1 or § 2 [of the Sherman Act], plaintiff [ ] must plead facts that support a plausible inference that the exclusive dealing arrangement forecloses a substantial share of the relevant market."); *Microsoft Corp. v. Computer Support*

Servs. of Carolina, Inc., 123 F. Supp. 2d 945, 954 (W.D.N.C. 2000) (granting motion to dismiss for failure to state market foreclosure claim under § 1 because plaintiff "made no attempt to define the 'market foreclosed' by [the defendant], . . . or explain how [the defendant] has foreclosed it from entering this unformulated market.").

B. Plaintiffs Do Not Allege They Lacked Alternative Means of Reaching the Market.

The Complaint is most notable for what it does not allege: Nowhere do Plaintiffs say there are no alternative means by which to administer treprostinil subcutaneously other than the CADD-MS 3 pump.

To be sure, Plaintiffs do allege that "*[c]urrently*, PAH patients who are prescribed subcutaneous treprostinil injections receive their Remodulin injections only through the CADD-MS 3 pump," Compl. ¶ 20 (emphasis added), and that "[t]here are no other medical devices that are *currently being used* to administer subcutaneous treprostinil injections in the United States," *id.* ¶ 21 (emphasis added). Even accepting those allegations as true, it would hardly be surprising that the drug developed by UTC is administered using the subcutaneous device that UTC selected and funded. *Id.* ¶ 61. But although those carefully worded passages seek to create the *impression* that the CADD-MS 3 is the only pump suitable for that purpose, Plaintiffs do not and cannot allege this critical fact. Plaintiffs' allegation that Remodulin patients currently do not use subcutaneous pumps other than the CADD-MS 3 should not be confused with the critical but missing allegation that there are no alternatives to the CADD-MS 3.

Plaintiffs' failure to allege a lack of alternative pumps is no mere oversight: Sandoz and RareGen do not allege they made any effort whatsoever to secure a supply of any pump or cartridge during the *eight-plus years* since Sandoz filed its treprostinil ANDA, or even in the nearly four years since Sandoz knew it would be legally permitted to enter the treprostinil market

in June 2018. *See* Compl. ¶ 39 (referencing settlement of ANDA litigation "in 2015"—nearly contemporaneous with Smiths's end-of-life notice). Nor do they allege any reason they could not have invested time and money into securing an alternative pump at a much earlier point. They in fact admit that such efforts, had they undertaken them, would have been rewarded with viable options to the CADD-MS 3 when they catalogue UTC's partnerships with no fewer than four different manufacturers over the last several years to develop numerous alternatives to the CADD-MS 3. *Id.* ¶¶ 40–44. Even if (contrary to fact) there were no suitable alternative pump, Plaintiffs never explain why they could not have done the same thing UTC has done and is doing: investing time and money to develop a pump.

At bottom, Plaintiffs are asking the Court to order Defendants to give their would-be competitors free rides on the fruits of Defendants' own labor, investment, and acumen.[5] That is antithetical to the antitrust laws, particularly when a competitor, through the same efforts, could achieve the same thing. *See, e.g.*, *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 409 (3d Cir. 2015) (citing *Verizon Commc'ns v. Trinko, LLP*, 540 U.S. 398, 408 (2004), for the proposition that competitors have the right "freely to exercise [their] own independent discretion as to parties with whom [they] will deal"). As the Supreme Court has warned, "[c]ompelling . . . firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities." *Trinko*, 540 U.S. at 407–08.

[5] Plaintiffs invoke UTC's work developing new and innovative pump technologies in order to complain that UTC will offer those pumps—which are the culmination of UTC's investment of tens of millions of dollars and countless hours of effort—for use only with Remodulin, as if UTC instead should be handing the fruits of its labor to its competitors to assist them in competing against UTC. Compl. ¶¶ 40, 42, 44.

C. Courts Dismiss Antitrust Claims for Failing To Allege There Is No Alternative Means of Reaching the Market.

Plaintiffs' failure to allege antitrust claims mirrors the fundamental flaws that warranted dismissal in *International Construction Products LLC v. Caterpillar Inc.* In that case, an importer of construction equipment partnered with an online marketplace to sell equipment purchased from certain manufacturers directly to end users. 2016 WL 264909, at *1. The manufacturers allegedly imposed exclusivity restrictions barring their dealers from dealing with competing suppliers, and threatened to stop selling equipment through the online marketplace if it continued to do business with the importer. *Id.* The importer sued for antitrust violations, claiming that the manufacturers engaged in unlawful exclusive dealing arrangements that foreclosed "substantial portions of the dealer market" by "impos[ing] 'all or nothing' terms on dealers." *Id.* at *5. Yet the court found that the importer failed to allege a *prima facie* case of exclusive dealing because it "fails to adequately plead the lack of alternative channels of distribution," and instead, "acknowledges multiple alternative means of distribution," "dismisses these alternatives as inferior," and "simply concludes—without any relevant factual support—that it is deprived of any feasible way to reach consumers." *Id.* (internal quotation marks omitted). Likewise, Plaintiffs here have failed to plead support for the naked claim that because the CADD-MS 3 cartridges allegedly are not available to them, they have no way to distribute their product to patients who use treprostinil subcutaneously.

Other courts agree that a plaintiff does not plead market foreclosure if it fails to allege the lack of viable alternative means of accessing the market. For example, in *Genus Lifesciences Inc. v. Lannett Co.*, 2019 WL 1981186 (N.D. Cal. May 3, 2019), both the defendant and plaintiff manufactured nasal sprays but defendant allegedly falsely promoted its spray as a "topical" treatment on a specific pharmaceutical price list. The plaintiff alleged that the defendant

unlawfully foreclosed market entry by competitors because customers searching for or reordering defendant's product by name or category would not see plaintiff's new product listed as an alternative. *Id.* at *4. Assuming for purposes of the motion that the defendant made false statements to describe its product, the court nevertheless dismissed the monopolization claim because the allegations related to "only a single promotional channel," and therefore "cannot give rise to a monopolization claim because if competitors can reach the ultimate consumers of the product by employing existing or potential alternative channels of distribution, it is unclear whether such restrictions foreclose from competition any part of the relevant market." *Id.* at *15; *see also Syncsort Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 332 (D.N.J. 1999) (dismissing claim because party "did not state in its pleadings the sorting product [at issue] is unique and cannot be interchanged with other sorting products") (citing *Queen City Pizza, Inc. v. Domino's Pizza*, 124 F.3d 430, 436 (3d Cir. 1997)). So too here, Plaintiffs claim that they have been foreclosed from the generic treprostinil market because a single distribution mechanism is not available to them, but that does not constitute market foreclosure. That incomplete pleading does not state a viable antitrust claim.

Plaintiffs allege that UTC and Smiths entered into exclusive arrangements with each other and with distributors and pharmacies as to the sale and use of CADD-MS 3 pumps and cartridges, and that such arrangements prevented Sandoz and RareGen from obtaining CADD-MS 3 pumps and cartridges that they might otherwise have used to distribute their product to patients. But they never allege—and they cannot allege—that there are no alternatives to the CADD-MS 3 pump or cartridges. Thus, whatever harm Plaintiffs claim to have suffered, it is not harm that is cognizable under the antitrust laws. Plaintiffs' antitrust claims should be dismissed.

II. Plaintiffs Fail To State Viable Antitrust Claims Because the Complaint Demonstrates Defendants Did Not Engage in Anticompetitive Conduct.

Plaintiffs fail to state valid antitrust claims for the additional reason that the conduct in which Defendants allegedly engaged cannot as a matter of law be characterized as anticompetitive. Although Plaintiffs attempt to paint Defendants' alleged acts as illicit efforts to prevent competition from a generic rival, the antitrust laws recognize that this conduct—which increased output and protected UTC's investment—was legitimate, procompetitive activity.

The Complaint makes clear that the supply arrangement between UTC and Smiths increased output for both pumps and cartridges. Smiths had announced, in 2015, that it would stop making the CADD-MS 3 pump and cartridges. Compl. ¶ 51. UTC stepped up to prevent Smiths from shutting down production by funding the production of additional supplies of pumps and cartridges to be made available to Remodulin patients. *Id.* Without UTC's intervention and investment, the cartridge supply to which Plaintiffs now claim entitlement would not exist at all. *Id.* As the Complaint makes clear, it was in this context that UTC and Smiths agreed the supply created by UTC's funding would be reserved "'for use with branded Remodulin only.'" *Id.*

Because UTC's collaboration with Smiths made possible the creation of these cartridges, UTC had every right to place restrictions on how that supply could be used. The law has long recognized that restrictions aimed at preventing competitors from free-riding on a rival's efforts and investments are legitimate and competition-enhancing.[6] "A collaboration that increases

[6] *See, e.g.*, *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 724–25 (1988) (vertical restrictions have "real potential to stimulate interbrand competition" by allowing manufacturer to achieve efficiencies in distribution that can be used "'to induce competent and aggressive retailers'" to invest in capital, labor, promotional activities, and other services, which otherwise might be deterred due to "'the so-called free rider effect'") (quoting *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 (1977)); *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S.

output and that 'makes possible the very activity that is allegedly restrained' is procompetitive and reasonable under the antitrust laws." *Gemini Concerts v. Triple A Baseball Club Assocs.*, 664 F. Supp. 24, 26–27 (D. Me. 1987) (contract is procompetitive when it "makes possible production that would not otherwise occur at all," and party that "invested a significant sum in capital improvements . . . has a legitimate interest in preventing its competitors from taking a free ride on its investment"). Neither UTC nor Smiths had any obligation to make these supplies available to Plaintiffs. *See, e.g.*, *Ohio v. Am. Express*, 138 S. Ct. 2274, 2289–90 (2018) ("nothing inherently anticompetitive" about vertical restrictions imposed by credit card company on retailers to prevent merchants from steering customers to other credit cards, because those restrictions safeguarded the company's investments and did not prevent competitors from offering lower fees or promoting broader merchant acceptance); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 890–91 (2007) (vertical restraints can prevent free riding, increasing availability of "tangible or intangible services or promotional efforts" that enhance competition and consumer welfare); *Olympia Equip. Leasing Co. v. W. Union Telegraph Co.*, 797 F.2d 370, 375 (7th Cir. 1986) (even "a firm with lawful monopoly power has no general duty to help its competitors").

Plaintiffs' claims boil down to a request that this Court force a business rival, UTC, to make available to Plaintiffs a specific cartridge supply that Plaintiffs concede only exists in the first place because UTC took action to forestall Smiths's shutting down production. It would be inimical to the policies underlying the antitrust laws to force Defendants to make the CADD-MS

752, 762–63 (1984) (manufacturers have legitimate interests in communicating with distributors and setting restrictions on sales of their products to ensure "that 'free-riders' do not interfere") (citing *Sylvania*, 433 U.S. at 55).

3 cartridges (or pumps) available to Plaintiffs under these circumstances.[7] That would encourage firms to sit back and do nothing while their competitors expend considerable resources to secure necessary supply, and then simply sue their competitors for access to the fruits of their labor—in other words, precisely what the Complaint demonstrates Sandoz and RareGen did here. A legal construct that would permit such free-riding would discourage companies in UTC's shoes from making investments to better serve consumers and increase consumer welfare. *Cf. Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 221–22 (D.C. Cir. 1986) (efforts to eliminate "the problem of the free ride" promote market efficiency and increase "effectiveness in serving consumers").

III. RareGen Lacks Antitrust Standing.

The Court should dismiss all antitrust claims asserted by RareGen for the additional reason that RareGen lacks antitrust standing. The doctrine of antitrust standing ensures that a "plaintiff is a proper party to bring a private antitrust action." *Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters ("AGC")*, 459 U.S. 519, 535 n.31 (1983); *Gulfstream III Assocs. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 429 (3d Cir.1993). It is a threshold requirement to bring suit under the Clayton Act, which provides for a private right of action under most antitrust statutes, including the Sherman Act. *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 264–65 (3d Cir. 1998). RareGen lacks antitrust standing because its alleged injuries are far too remote from the conduct that Plaintiffs allege is anticompetitive.

In this Circuit, courts use a five-factor test, first enunciated by the Supreme Court in

[7] *See, e.g.*, *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (quoting and citing cases for proposition that it is "inimical to the antitrust laws to award damages for losses stemming from continued competition") (alterations and citations omitted); *see also Philadelphia Taxi Ass'n, Inc. v. Uber Techs., Inc.*, 886 F.3d 332, 338 (3d Cir. 2018) (same).

AGC, to determine whether an antitrust plaintiff can establish antitrust standing:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165–66 (3d Cir.1993) (citing *AGC*, 459 U.S. at 545).

It was Sandoz—not RareGen—that filed the ANDA for generic treprostinil and obtained approval from the FDA to market that drug. Compl. ¶ 34. Under an alleged August 2018 agreement with Sandoz, RareGen serves as Sandoz's sales representative for generic treprostinil. Compl. ¶ 45 ("RareGen has the exclusive right to encourage the appropriate use of generic treprostinil injections," and "is responsible for establishing sales representatives and educating and supporting . . . medical professionals with prescribing authority," while "Sandoz is responsible for maintaining a sufficient supply of generic treprostinil").

Sales representatives and other similar intermediaries lack antitrust standing to pursue antitrust claims based on harm as to the product that they sell, because they are neither consumers nor competitors, and their alleged injuries are both too remote and wholly derivative of those suffered by the product manufacturer. *See McCullough v. Zimmer*, *Inc.*, 382 F. App'x 225, 229–30 (3d Cir. 2010); *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10–11 (1st Cir. 1999); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, 2016 WL 7805628, at *15 (N.D. Cal. Aug. 4, 2016) (citing *McCullough*, 382 F. App'x at 229); *Dish Network, LLC. v. Fun Dish Inc.*, 2010 WL 5230861, at *7 (N.D. Ohio July 30, 2010). Here, RareGen fails the test for antitrust standing for multiple reasons.

First, RareGen fails to meet the second *AGC* standing element inasmuch as it has failed to allege an antitrust injury because its supposed harm arose, as discussed above, from purely legitimate competitive conduct undertaken by Defendants—*i.e.*, investing in expanded cartridge output that would not otherwise exist and preventing RareGen from free riding on this supply. *See, e.g.*, *Atl. Richfield*, 495 U.S. at 334 (injury caused by continued competition does not qualify as antitrust injury); *Brunswick*, 439 U.S. at 488–89 (same); *Philadelphia Taxi Ass'n*, 886 F.3d at 344 (same). Moreover, among other reasons, RareGen fails to satisfy the third, fourth, and fifth *AGC* standing elements—the causal connection between the alleged antitrust violation, RareGen's alleged harm, and Defendants' alleged intent is highly attenuated, if it exists at all, and RareGen's injury, if any, would be entirely derivative of Sandoz's. *See, e.g.*, *In re Cathode Ray Tube*, 2016 WL 7805628 at *15 (intermediary's "injury (to the extent it is injured at all) is indirect; there is a high risk that the agent and the principal will secure duplicative recoveries; and the principal is the more direct victim").

Accordingly, Plaintiff RareGen's antitrust claims should be dismissed for this additional, independent reason.

IV. The Court Should Dismiss Plaintiffs' State Law Claims Because the Antitrust Claims on Which They Are Predicated Fail and Because They Are Duplicative.

A. Plaintiffs Fail To Allege State Claims for Restraint of Trade and Unfair Trade Practices.

Plaintiffs' antitrust pleading deficiencies discussed above apply with equal force to their state law claims for restraint of trade and unfair trade practices. In the alternative, even if this Court allows Plaintiffs to advance their federal antitrust claims, Counts III, IV, and V should still be dismissed as redundant of Plaintiffs' Sherman Act claim in Count 1.

Plaintiffs' state and federal claims are functionally identical. Plaintiffs rely upon the same facts in pleading each of these claims. *See* Compl. ¶¶ 78–82, 88–99. Plaintiffs request the same undifferentiated relief for each claim. *See id.* ¶ 105. This is hardly surprising, as the law is the same for each of the claims. As a starting point, the text of each state's antitrust statutes is materially identical to that of the Sherman Act.[8] The states expressly modeled their laws on the Sherman Act. *See, e.g.*, *Urdinaran v. Aarons*, 115 F. Supp. 2d 484, 492 (D.N.J. 2000) ("New Jersey [Antitrust] Act was modeled on the Sherman Act") (citation omitted)*; Carolina Rest. Grp., Inc. v. Pepsico Sales, Inc.*, 2015 WL 4250395, at *7 (W.D.N.C. July 13, 2015) ("North Carolina's law is modeled" after Section 1 of the Sherman Act). The fact that the federal claim includes an additional element—the Sherman Act's interstate commerce impact requirement—is immaterial because it is not disputed here that Defendants sold products in interstate commerce. *See Murrow Furniture Galleries, Inc. v. Thomasville Furniture Indus., Inc*., 889 F.2d 524, 530 (4th Cir. 1989) (affirming dismissal of North Carolina antitrust claim where impact on interstate commerce was not disputed).

The body of law interpreting and applying these state and federal laws, moreover, is the same. New Jersey's state legislature enacted a harmonization statute that the state's antitrust act "shall be construed in harmony with ruling judicial interpretations of comparable Federal antitrust statutes and to effectuate, insofar as practicable, a uniformity in the laws of those states which enact it." N.J. Stat. Ann. § 56:9-18. Consistent with that dictate, the Third Circuit applies

[8] *Compare* N.J. Stat. Ann. § 56:9-3 ("Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce, in this State, shall be unlawful.") *and* N.C. Gen. Stat. § 75-1 ("Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the State of North Carolina is hereby declared to be illegal.") *with* 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

the federal and New Jersey antitrust laws identically. *See Eisai*, 821 F.3d at 402 n.11. Similarly, North Carolina courts hold that "[f]ederal case law interpretations of the federal antitrust laws are persuasive authority in construing [North Carolina] antitrust statutes," *Hyde v. Abbott Labs., Inc.,* 473 S.E.2d 680, 684 (N.C. Ct. App. 1996), and that "the body of law applying the Sherman Act" is "instructive in determining the full reach" of the state's analogous statute. *Rose v. Vulcan Materials Co.*, 194 S.E.2d 521, 530 (N.C. 1973). Accordingly, when dismissing federal antitrust claims at the motion to dismiss stage, courts rely on an identical analysis to dismiss New Jersey and North Carolina antitrust claims. *See, e.g.*, *Shire US, Inc. v. Allergan, Inc*., 2019 WL 1349828, at *17 (D.N.J. Mar. 22, 2019) (New Jersey antitrust law); *St. Clair v. Citizens Fin. Grp.*, 2008 WL 4911870, at *6 (D.N.J. Nov. 12, 2008), *aff'd*, 340 F. App'x 62 (3d Cir. 2009) (New Jersey antitrust law); *Sewell Plastics, Inc. v. Coca–Cola Co*., 720 F. Supp. 1196, 1220 (W.D.N.C. 1989) (dismissing federal and North Carolina antitrust claims at summary judgment), *aff'd*, 912 F.2d 463 (4th Cir. 1990).

Plaintiffs' North Carolina unfair trade practices claim also fails for the same reasons as the federal antitrust claims. To "plead a claim under the UDTPA, [Plaintiffs] must allege that (1) the defendant engaged in unfair or deceptive conduct, (2) that conduct affected commerce, and (3) [Plaintiffs were] proximately harmed as a result." *Pfendler v. PNC Bank, Nat'l Ass'n*, 2019 WL 1306875, at *2 (3d Cir. Mar. 21, 2019). Although "some courts have interpreted North Carolina General Statutes Section 75-1.1 to prohibit commercial unfairness and deception beyond traditional antitrust concepts," *R. J. Reynolds Tobacco Co. v. Philip Morris Inc.*, 199 F. Supp. 2d 362, 396 (M.D.N.C. 2002), *aff'd sub nom. RJ Reynolds Tobacco Co. v. Philip Morris USA, Inc.*, 67 F. App'x 810 (4th Cir. 2003) (internal citations omitted), Plaintiffs' sole allegation for deceptive and unfair conduct here is the alleged anticompetitive conduct that forms the basis

of their antitrust claims. Compl. ¶ 93. *Cf. Livingston v. Trane Inc.*, 2019 WL 397982, at *8 (D.N.J. Jan. 31, 2019) (dismissing North Carolina unfair trade practices claim based on other claims that were not properly pleaded).

In the alternative, even if the Court were to allow Plaintiffs' antitrust claims to proceed to discovery, it ought to streamline the case by dismissing Plaintiffs' redundant state law claims. "Redundant pleading, which is not permitted, pleads as separate claims causes of action with identical elements and potential relief." *US LEC Commc'ns LLC v. Qwest Commc'ns Co.*, 2011 WL 2474262, at *4 (D.N.J. June 20, 2011); *see also Blake Gardens, LLC v. New Jersey*, 309 F. Supp. 3d 240, 248 (D.N.J. 2018) ("It is well-recognized that a court may dismiss a duplicative claim in a complaint.") (*quoting Slimm v. Bank of Am. Corp.*, 2013 WL 1867035, at *22 (D.N.J. May 2, 2013)); *Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) (striking redundant claims). The test for redundancy is whether the alternative claim involves a variation in the facts, law, or relief sought. *See US LEC Commc'ns LLC*, 2011 WL 2474262, at *4. No such variation exists here.

Plaintiffs' state law unfair practices claims ought to be dismissed under all circumstances: they fail because they share the same infirmities as Plaintiffs' federal antitrust claims, and for the additional independent reason that they are duplicative of the federal claims.

B. Plaintiffs Fail To Allege a Claim for Tortious Interference with Prospective Business Advantage.

Plaintiffs' tortious interference with prospective economic advantage claim fails because it relies on the deficient antitrust claims as the sole basis for overcoming Defendants' competitor privilege. Defendants have a privilege to interfere with their competitors' prospective economic relations—meaning "there is no compensable tort injury"—if "a plaintiff's loss of business is merely the incident of healthy competition." *Ideal Dairy Farms v. Farmland Dairy Farms*, 659

A.2d 904, 933 (N.J. Super. Ct. App. Div. 1995) (citation omitted).[9] Under this privilege, an actor may intentionally cause a third party not to enter into a prospective contractual relation with the actor's competitor if:

> (a) the [prospective] relation concerns a matter involved in the competition between the actor and competitor and
>
> (b) the … actor does not employ wrongful means and
>
> (c) [the actor's] action does not create or continue an unlawful restraint of trade and
>
> (d) [the actor's] purpose is at least in part to advance his interest in competing with the other.

Coast to Coast Entm't, LLC v. Coastal Amusements, Inc., 2005 WL 7979273, at *22 (D.N.J. Nov. 7, 2005) (*citing E Z Sockets v. Brighton-Best Socket Screws Mfg. Inc.*, 704 A.2d 1364, 1370 (N.J. Super. Ct. Ch. Div. 1996)). These are affirmative elements of a plaintiff's claim. Therefore, to state a claim for tortious interference, the plaintiff must plead there is no competitor privilege. *Intervest Fin. Servs., Inc. v. S.G. Cowen Sec. Corp*., 206 F. Supp. 2d 702, 721 n.21 (E.D. Pa. 2002), *aff'd sub nom. InterVest, Inc. v. Bloomberg, LP*, 340 F.3d 144 (3d Cir. 2003).

Plaintiffs fail to carry their burden. They identify Defendants as competitors of Plaintiffs engaged in stifling a potential relation pertinent to the competition. Compl. ¶ 46. They also plead that the purpose of Defendants' alleged conduct, at least in part, was to promote UTC's

[9] Plaintiffs do not identify any particular state's law for their tortious interference claim. For purposes of this motion, we assume that this Court will apply the law of the forum because the elements of tortious interference with prospective business advantage are nearly identical, so there probably is not a material conflict of laws. *See, e.g.*, *GFI, Inc. v. Bean Station Furniture*, 286 F. Supp. 2d 663, 666 n.1 (M.D.N.C. 2003) ("The elements of tortious interference with prospective economic advantage are: (1) defendant induced a third party to refrain from entering into a contract with plaintiff; (2) a contract would have ensued but for the interference; (3) defendant acted without justification.") (*citing Cameron v. New Hanover Mem'l Hosp*., 293 S.E.2d 901, 917 (N.C. Ct. App. 1982)).

own sales at the expense of generic competitors. *Id.* ¶ 50. And as with the unfair and deceptive practices claim, Plaintiffs rely solely on the antitrust allegations for their allegations of "wrongful means" and "unlawful restraint on trade." Therefore, because Plaintiffs' antitrust claims fail, and there was not wrongful means or unlawful restraint, their tortious interference claim necessarily fails as well.

CONCLUSION

More than three years ago, UTC took action to ensure that CADD-MS 3 pumps and cartridges would remain available to patients using Remodulin. During those same years, Plaintiffs did nothing to ensure that pumps and cartridges would be available to support the launch of their generic drug. Now Plaintiffs ask the Court to rescue them from their negligence and to require UTC to provide its competitors what they could and should have obtained through diligence and effort. Plaintiffs' attempt to free-ride on Defendants' investment in the creation of CADD-MS 3 pumps and cartridges suffers from numerous, incurable pleading defects, as detailed above. The Court should dismiss Plaintiffs' Complaint in its entirety for failure to state a claim.

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